## REMARKS

Reconsideration by the Examiner is respectfully requested in light of the foregoing amendments and the following comments.

Claims 1, 2, 6, 10, 12, 13, 22, 23, 25-29, 32-35, 37 and 38 remain in the application. The arguments made herein respond in the order of the rejections discussed in the Appeal Board decision.

Claim 1 has been amended to more clearly recite the nature of the insolubility and claim 12 has also had a minor amendment made therein.

Final Rejections

I. Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34 and 38 rejected under 35 U.S.C. §102(b) as being anticipated by Ruys.

II. Claims 10 and 26 rejected under 35 U.S.C. §103(a) as being obvious over Ruys.

III. Claims 27, 29, 35 and 37 rejected under 35 U.S.C. §103(a) as being obvious in view of the combined teachings of Ruys and Davies.

IV. Claim 33 rejected under 35 U.S.C. §103(a) as being obvious over the combined teachings of Ruys and Kijima.

I. Ruys dopes HAp with silicon. As discussed on page 74 of Ruys in the Methods and Materials section, Hap was synthesized in a process involving a stir/boil method. This method was done to "eliminate TCP from the calcined product. This could not be achieved reliably with cold-stirring for the recommended time..". The resulting precipitates were identified as HAp crystallites that were resuspended in ethanol to which tetraethyl orthosilicate was added. This mixture was then subjected to high-speed stirring. The mixture was evaporated to form a filter cake that was sintered at 1100°C for

1 hour. The phase analysis indicated that the silicon dioxide can induce a HAp to TCP decomposition. However, the "TCP" is an undesirable phase since it is biodegradable *in vivo*. It was stated that using the method some alpha-TCP were formed as is listed in the conclusions at page 79 of Ruys. Here it is stated that four products were formed by their method:

- calcium silicophosphate
- tricalcium phosphate
- silicon-doped HAp
- Si-P-O glass

Ruys produces four products stating that the TCP content should be kept "to a minimum and so eliminate the possibility of biodegradability *in vivo*".

To summarize, Ruys teaches a method to produce a mixture of four compounds one of which is identified to be a soluble tricalcium phosphate. The method specifically states that a stir/boil method should be done to avoid TCP from the calcined product. The calcined product is the final product. Even with this specific instruction to avoid the formation of TCP some soluble TCP is stated to be formed. Thus Ruys himself teaches specifically not to form TCP and devises a method to do so. And further, teaches that the TCP that is formed using his specific method is soluble.

In contrast, the present invention claims an insoluble tricalcium phosphate. Claim 1 recites that the composition:

- supports bone activity for osteoblast secretion/osteoclast resorption; and
- comprises insoluble alpha-TCP.

The presently claimed composition is made by mixing a HA sol-gel with the dopant. The mixture is dried and sintered. The HA sol-gel is NOT subjected to any stir/boil method as is specifically taught to do by Ruys. As a result, the present claimed invention is desirious of producting not only an alpha-TCP but one that is insoluble in physiological media and this is completely contrary to Ruys own teachings.

It is submitted that the processing conditions of Ruys and the Applicant are indeed different as is described *supra* and this difference is because Ruys admits that he does not wish to produce any TCP. This difference is also because any residual TCP produced by Ruys is stated to be soluble. The difference in methods leads the Applicant to form a stabilized and insoluble alpha-TCP that is also bioactive with respect to osteoblast and osteoclast activity.

Therefore none of the noted claims can be anticipated by Ruys by the documents own admission. Since the methodology is different, Ruys does not inherently produce the claimed composition. The Applicants need not provide further evidence since Ruys himself teaches a different methodology, a different product and has a different purpose for his published work.

II. With respect to claims 10 and 26, these claims all depend from claim 1 and as such recite the same novel properties. As discussed *supra*, Ruys teaches away from forming TCP and is SILENT with respect to the teaching or suggestion of an insoluble TCP. Ruys teaches a method to make silicon-doped HA that is different to that of the Applicants and as such, leads to a different product with different characteristics as Ruys admits. For these reasons, these claims cannot be obvious in view of the teachings of Ruys.

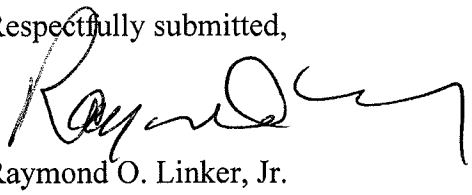
III. With respect to the rejection of claims 27, 29, 35 and 37, Ruys has been discussed in detail *supra*. Davies teaches sintering the HA-sol on a quartz substrate resulting in a variety of different phases across the thin film composition. Davies does not teach any deliberate doping of the sol-gel and the formation of any type of uniformly stabilized alpha-TCP as is recited in claim 1 from which these claims depend therefrom. Specifically claim 27 is directed to an implantable calcified bone matrix. Davies merely teaches an *in vitro* diagnostic device. Davies does not teach or suggest any type of implantable device for use *in vivo*. Davies also does not teach or suggest an *ex vivo* method to engineer an implant that uses the composition of claim 1.

The combination of these two documents does not provide for each and every element of the claims nor does the combination of the teachings of the two documents specifically suggest making any combination remotely close to that of these claims. As such, these documents taken together cannot render obvious these noted rejected claims.

IV. With respect to the rejection of claim 33, Ruys has been discussed in detail *supra*. Kijima merely discloses the use of a zirconia-TCP coating on a zirconia implant. So while Kijima may suggest the use of TCP as a coating on an implant, Kijima does not teach or suggest any type of stabilized and insoluble bioactive alpha-TCP as is presently claimed. Thus the combination of Ruys and Kijima together cannot render obvious claim 33.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



Raymond O. Linker, Jr.
Reg. No. 26,419

**ALSTON & BIRD LLP**
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111
LEGAL01/13045375v1